

MOTION UNDER 28 U.S.C. § 2255 TO VACATE, SET ASIDE, OR CORRECT  
SENTENCE BY A PERSON IN FEDERAL CUSTODY

15-CV-6808

<b>United States District Court</b>		District <b>EASTERN DISTRICT OF PENNSYLVANIA</b>
Name (under which you were convicted): <b>Kermit B. Gosnell</b>		Docket or Case No.: <b>11-CR-727-1</b>
Place of Confinement: <b>SCI Huntingdon</b>	Prisoner No.: <b>LJ 1445</b>	
UNITED STATES OF AMERICA		Movant (include name under which convicted) <b>V. Kermit B. Gosnell</b>

**MOTION**

1. (a) Name and location of court which entered the judgment of conviction you are challenging: United States District Court for the Eastern District of Pennsylvania  
  


(b) Criminal docket or case number (if you know): 11-CR-727-1
2. (a) Date of the judgment of conviction (if you know): 12/16/2013  
 (b) Date of sentencing: 12/16/2013
3. Length of sentence: 360 months
4. Nature of crime (all counts): 21:846 Conspiracy to distribute controlled substances, CT.1  
21:841 (A)(1), (B)(2), and (B)(3) & 18.2 Distribution of  
CDS and aiding and abetting, cts.2-11  
21:856 (A)(10) maintaining a place for illegal distribution of  
CDS, CT.22
5. (a) What was your plea? (Check one)  
 (1) Not guilty ☐      (2) Guilty ☒      (3) Nolo contendere (no contest) ☐

Sentence procedure: 3559 PLRA Sentence

 (b) If you entered a guilty plea to one count or indictment, and a not guilty plea to another count or what did you plead guilty to and what did you plead not guilty to?  
As per letter to the Presiding Judge of November 9, 2013,  
entitled "Response to Presentance Investigation Report", and with  
verification document of September 9, 2015, petitioner pleaded  
guilty to inadequate supervision of office staff which allowed  
diversion. Petitioner continues to profess innocence of "pill mill".
6. If you went to trial, what kind of trial did you have? (Check one)      Jury ☐      Judge only ☐

7. Did you testify at a pretrial hearing, trial, or post-trial hearing? Yes ☒ No ☐
8. Did you appeal from the judgment of conviction? Yes ☒ No ☐
9. If you did appeal, answer the following:
- (a) Name of court: United States Court of Appeals for the Third Circuit
- (b) Docket or case number (if you know): Appeal # 14-1069
- (c) Result: Grant the Government's Motion for Summary Affirmance
- (d) Date of result (if you know): July 15, 2014
- (e) Citation to the case (if you know): U.S. vs. Goodson 544 F.3d 529 (3d Cir. 2008)
- (f) Grounds raised: There were no benefits which resulted from the guilty plea and appellate waiver.
- (g) Did you file a petition for certiorari in the United States Supreme Court? Yes ☒ No ☐
- If "Yes," answer the following:
- (1) Docket or case number (if you know): DPAE 2-11CR00727-001
- (2) Result: Petition Denied
- (3) Date of result (if you know): November 10, 2014
- (4) Citation to the case (if you know): Citation not known
- (5) Grounds raised: Because the Judge advised that there were benefits which resulted from the guilty plea and appellate waiver, and because there were no benefits which resulted from the guilty plea and appellate waiver, the government did not meet its burden of proving that the waiver of appellate rights was a knowing waiver. For this reason, the government's motion to enforce the appellate waiver should have been denied.
10. Other than the direct appeals listed above, have you previously filed any other motions, petitions, or applications, concerning this judgment of conviction in any court? Yes ☒ No ☐
11. If your answer to Question 10 was "Yes," give the following information:
- (a) (1) Name of court: U.S. District Court - Eastern District of PA
- (2) Docket or case number (if you know): 11-CR-727-1

- (3) Date of filing (if you know): September 9, 2015
- (4) Nature of the proceeding: Motion to Obtain Court Documents & Transcripts
- (5) Grounds raised: \_\_\_\_\_

Documents necessary to perfect collateral challenge

Listing of Issues of Arguable Merit

Request for Assistance of Counsel

Verification of "Response to Presentance Investigation Report"

Request for 10% sampling of medical records to verify.

- (6) Did you receive a hearing where evidence was given on your motion, petition, or application?

Yes ☐ No ☒

- (7) Result: Denied without prejudice

- (8) Date of result (if you know): November 20, 2015

- (b) If you filed any second motion, petition, or application, give the same information:

- (1) Name of court: U.S. District Court - Eastern District of PA

- (2) Docket of case number (if you know): 11-CR-727-1

- (3) Date of filing (if you know): October 19, 2015

- (4) Nature of the proceeding: Motion for Extension of § 2255 Filing Deadline

- (5) Grounds raised: \_\_\_\_\_

Complexity of Federal and State proceedings

Lack of requested Court documents

Stress and strain

Request for Assistance of Counsel

- (6) Did you receive a hearing where evidence was given on your motion, petition, or application?

Yes ☐ No ☒

- (7) Result: Granted in part and denied in part

- (8) Date of result (if you know): November 20, 2015

- (c) Did you appeal to a federal appellate court having jurisdiction over the action taken on your motion, petition, or application?

- (1) First petition: Yes ☐ No ☒

- (2) Second petition: Yes ☐ No ☒

- (d) If you did not appeal from the action on any motion, petition, or application, explain briefly why you did not:

Time constraints of completing and filing motion under § 2255  
by the extension deadline of December 18, 2015

12. For this motion, state every ground on which you claim that you are being held in violation of the Constitution, laws, or treaties of the United States. Attach additional pages if you have more than four grounds. State the facts supporting each ground.

**GROUND ONE: CONVICTION OBTAINED BY USE OF COERCED CONFESSION**

- (a) Supporting facts (Do not argue or cite law. Just state the specific facts that support your claim.):

Petitioner was coerced to plead guilty and waiver the right to appeal. The expectation of the defendant was to take responsibility for inadequate supervision which allowed illegal abuses by the office staff of his Pain Management Program. All allegations to a "Pill Mill" were consistently and vigorously denied. The waiver of the right to appeal was not made knowingly, willingly and intelligently. It was anticipated that retained counsel would substantiate pain management methodology by presentation of medical record documentation, as was evidenced in every instance of the state criminal proceedings.

- (b) Direct Appeal of Ground One:

- (1) If you appealed from the judgment of conviction, did you raise this issue?

Yes ☐ No ☒

- (2) If you did not raise this issue in your direct appeal, explain why:

Research and due diligence in Law Library only began in spring of 2015, due to depressive reaction from criminal proceedings.

- (c) Post-Conviction Proceedings:

- (1) Did you raise this issue in any post-conviction motion, petition, or application?

Yes ☐ No ☒

- (2) If you answer to Question (c)(1) is "Yes," state:

Type of motion or petition: \_\_\_\_\_

Name and location of the court where the motion or petition was filed: \_\_\_\_\_

Docket or case number (if you know): \_\_\_\_\_

Date of the court's decision: \_\_\_\_\_

Result (attach a copy of the court's opinion or order, if available): \_\_\_\_\_

- (3) Did you receive a hearing on your motion, petition, or application?

Yes ☐ No ☐

(4) Did you appeal from the denial of your motion, petition, or application?

Yes ☐ No ☐

(5) If your answer to Question (c)(4) is "Yes," did you raise the issue in the appeal?

Yes ☐ No ☐

(6) If your answer to Question (c)(4) is "Yes," state:

Name and location of the court where the appeal was filed: \_\_\_\_\_

Docket or case number (if you know): \_\_\_\_\_

Date of the court's decision: \_\_\_\_\_

Result (attach a copy of the court's opinion or order, if available): \_\_\_\_\_

(7) If your answer to Question (c)(4) or Question (c)(5) is "No," explain why you did not appeal or raise this issue: \_\_\_\_\_

**GROUND TWO: Conviction obtained by denial of effective assistance**  
**of Counsel**

(a) Supporting facts (Do not argue or cite law. Just state the specific facts that support your claim.):

Petitioner was totally abandoned by retained Counsel. No  
contact or response to established lines of communication from  
signing of plea agreement until court sentencing. Counsel  
did not perform the essential due diligence to support and  
substantiate defendant's written affirmations of innocence,  
professional competence and the treatment approach to interventions  
in the management of pain.

(b) **Direct Appeal of Ground Two:**

(1) If you appealed from the judgment of conviction, did you raise this issue?

Yes ☐ No ☒



(2) If you did not raise this issue in your direct appeal, explain why: \_\_\_\_\_  
Research and due diligence in Law Library only began in spring  
of 2015, due to depressive reaction from criminal proceedings.

**(c) Post-Conviction Proceedings:**

(1) Did you raise this issue in any post-conviction motion, petition, or application?

Yes ☐ No ☒

(2) If you answer to Question (c)(1) is "Yes," state:

Type of motion or petition: \_\_\_\_\_

Name and location of the court where the motion or petition was filed: \_\_\_\_\_

Docket or case number (if you know): \_\_\_\_\_

Date of the court's decision: \_\_\_\_\_

Result (attach a copy of the court's opinion or order, if available): \_\_\_\_\_

(3) Did you receive a hearing on your motion, petition, or application?

Yes ☐ No ☐

(4) Did you appeal from the denial of your motion, petition, or application?

Yes ☐ No ☐

(5) If your answer to Question (c)(4) is "Yes," did you raise the issue in the appeal?

Yes ☐ No ☐

(6) If your answer to Question (c)(4) is "Yes," state:

Name and location of the court where the appeal was filed: \_\_\_\_\_

Docket or case number (if you know): \_\_\_\_\_

Date of the court's decision: \_\_\_\_\_

Result (attach a copy of the court's opinion or order, if available): \_\_\_\_\_

(7) If your answer to Question (c)(4) or Question (c)(5) is "No," explain why you did not appeal or raise this issue: \_\_\_\_\_

**GROUND THREE: Conviction obtained by unconstitutional failure of the****prosecution to disclose evidence favorable to the defendant.**

(a) Supporting facts (Do not argue or cite law. Just state the specific facts that support your claim.):

Especially in regard to the creditability of petitioner, the exculpatory data listed forthwith was known, or should have been known to the prosecution and was not presented: Curriculum vitae; Addictive Disease experience and publications; Educational literature for patients; Census of disabled veterans, cancer patients as well as those with complex medical/surgical problems; History of Petitioner's State and Federal regulatory compliance; Hospital and University Preceptorships and Agency evaluations for medical students, physician's assistants and Nurse Practitioners; Honorable Military Discharge to continue community medicine and interventions for substance abuse in an underprivileged area.

(b) **Direct Appeal of Ground Three: MEDICAL RECORDS WILL SHOW INNOCENCE OF MOVANT.**

(1) If you appealed from the judgment of conviction, did you raise this issue?

Yes ☐ No ☒

(2) If you did not raise this issue in your direct appeal, explain why:

Research and due diligence in law library only began in spring of 2015, due to depressive reaction from criminal proceedings.

(c) **Post-Conviction Proceedings:**

(1) Did you raise this issue in any post-conviction motion, petition, or application?

Yes ☐ No ☒

(2) If you answer to Question (c)(1) is "Yes," state:

Type of motion or petition: \_\_\_\_\_

Name and location of the court where the motion or petition was filed: \_\_\_\_\_

Docket or case number (if you know): \_\_\_\_\_

Date of the court's decision: \_\_\_\_\_

Result (attach a copy of the court's opinion or order, if available): \_\_\_\_\_

(3) Did you receive a hearing on your motion, petition, or application?

Yes ☐ No ☐

(4) Did you appeal from the denial of your motion, petition, or application?

Yes ☐ No ☐

(5) If your answer to Question (c)(4) is "Yes," did you raise the issue in the appeal?

Yes ☐ No ☐

(6) If your answer to Question (c)(4) is "Yes," state:

Name and location of the court where the appeal was filed: \_\_\_\_\_

Docket or case number (if you know): \_\_\_\_\_

Date of the court's decision: \_\_\_\_\_

Result (attach a copy of the court's opinion or order, if available): \_\_\_\_\_

(7) If your answer to Question (c)(4) or Question (c)(5) is "No," explain why you did not appeal or raise this issue: \_\_\_\_\_

**GROUND FOUR: NEW EVIDENCE in regard to Oxycontin Abuse**

(a) Supporting facts (Do not argue or cite law. Just state the specific facts that support your claim.):

The Physician's Desk Reference and pharmaceutical marketing professed that Oxycontin had protection from abuse because of its "inactive binders" and "extended release" formulation.

The fraudulent marketing of Purdue Pharma was not known to the petitioner until January, 2015. Prescriptions for Oxycontin, and especially renewals, would have been severely restricted if the potential for intravenous administration had been known.

(b) **Direct Appeal of Ground Four:**

(1) If you appealed from the judgment of conviction, did you raise this issue?

Yes ☐ No ☒

(2) If you did not raise this issue in your direct appeal, explain why:

This information is not known during the period of court appointed public defender, Daniel Siegel, Esquire.

(c) **Post-Conviction Proceedings:**

(1) Did you raise this issue in any post-conviction motion, petition, or application?

Yes ☐ No ☒



## GROUND FIVE: Defense of Justification

## (a) Supporting facts:

Although the pain management program experienced diversion and substance abuse, the decriminalization of addict behavior and treatment of the opiate dependant population is arguably a "lessor evil" and distinctly more humane to the population served by the petitioner.

- (b) this issue was not raised in any post-conviction; petition or application because research and due diligence in Law Library only began in spring 2015, due to depressive reaction from criminal proceedings.

## GROUND SIX: Conviction obtained by use of illegal seizure of life savings of Petitioner and his wife.

## (a) Supporting facts:

Parents of both petitioner and spouse of thirty years strongly advocated savings in cash, from family experiences during the depression. In addition, the bank accounts of this husband and wife had both been seized by Internal Revenue Service for late filings of the corporation for which petitioner had been Director.

- (b) this issue was not raised in any post-conviction motion, petition, or application because research and due diligence in Law Library only began in Spring, 2015, due to depressive reaction from criminal proceedings.

## GROUND SEVEN: Conviction obtained by use of insufficient jury instructions in State Court for the exceptional level of media sensationalism.

## (a) Supporting facts:

Media coverage was inordinately inflammatory and inherently prejudicial on local, national and international levels. The character and credibility of Defendant was so imbued that Due Process and Sentencing, in both State and Federal proceedings, were adversely and prejudicially affected by the public perception. Factual evidence was overwhelmed by frequently reinforced monstrous allegations.

- (b) this issue was not raised in any post-conviction motion, petition, or application because research and due diligence in Law Library only began in Spring, 2015, due to depressive reaction from criminal proceedings.

(2) If your answer to Question (c)(1) is "Yes," state:

Type of motion or petition: \_\_\_\_\_

Name and location of the court where the motion or petition was filed: \_\_\_\_\_

Docket or case number (if you know): \_\_\_\_\_

Date of the court's decision: \_\_\_\_\_

Result (attach a copy of the court's opinion or order, if available): \_\_\_\_\_

(3) Did you receive a hearing on your motion, petition, or application?

Yes ☐ No ☐

(4) Did you appeal from the denial of your motion, petition, or application?

Yes ☐ No ☐

(5) If your answer to Question (c)(4) is "Yes," did you raise the issue in the appeal?

Yes ☐ No ☐

(6) If your answer to Question (c)(4) is "Yes," state:

Name and location of the court where the appeal was filed: \_\_\_\_\_

Docket or case number (if you know): \_\_\_\_\_

Date of the court's decision: \_\_\_\_\_

Result (attach a copy of the court's opinion or order, if available): \_\_\_\_\_

(7) If your answer to Question (c)(4) or Question (c)(5) is "No," explain why you did not appeal or raise this issue: \_\_\_\_\_

13. Is there any ground in this motion that you have not previously presented in some federal court? If so, which ground or grounds have not been presented, and state your reasons for not presenting them:

All seven GROUNDS, submitted herein, are now presented in  
Federal Court for the first time. Prior to the due diligence  
in Law Library (beginning as stated in Spring, 2015), all  
of petitioners initiatives were focused on affirmation and  
support of innocence, rather than the constitutionality  
of due process.

17. **TIMELINESS OF MOTION:** If your judgment of conviction became final over one year ago, you must explain why the one-year statute of limitations as contained in 28 U.S.C. § 2255 does not bar your motion.\*

A Motion for Extension of Filing Deadline was submitted  
 on or about October 19, 2015 and GRANTED. It was ordered on  
 Jan 5, 2016 that petitioner shall complete the court's  
 standard form of petition within thirty days.

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\* 28 U.S.C. § 2255(f), provides that:

A one-year period of limitation shall apply to a motion under this section. The limitation period shall run from the latest of –

- (1) the date on which the judgment of conviction became final;
- (2) the date on which the impediment to making a motion created by governmental action in violation of the Constitution or laws of the United States is removed, if the movant was prevented from making such a motion by such governmental action;
- (3) the date on which the right asserted was initially recognized by the Supreme Court, if that right has been newly recognized by the Supreme Court and made retroactively applicable to cases on collateral review; or
- (4) the date on which the facts supporting the claim or claims presented could have been discovered through the exercise of due diligence.

Therefore, movant asks that the Court grant the following relief: \_\_\_\_\_

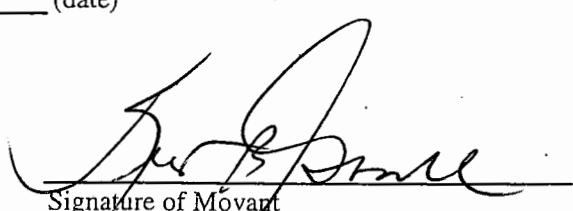
VACATE, SET ASIDE, OR CORRECT FEDERAL SENTENCE

\_\_\_\_\_ or any other relief to which movant may be entitled.

\_\_\_\_\_  
Signature of Attorney (if any)

I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct and that this Motion under 28 U.S.C. § 2255 was placed in the prison mailing system on January 31, 2016  
(month, date, year)

Executed (signed) on January 30, 2016 (date)

  
\_\_\_\_\_  
Signature of Movant

Kermit B. Gosnell

If the person signing is not movant, state relationship to movant and explain why movant is not signing this motion.

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## MEMORANDUM IN SUPPORT OF MOTION OF KERMIT B. GOSNELL, M.D.

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## INTRODUCTION:

Fueled by complaints and accusations by a disgruntled employee (secondary to disciplinary action); and fueled by testimonies of several employees under investigation for prescription diversion; and fueled by cardiac arrest and "accidental death" of a patient with an otherwise uncomplicated therapeutic abortion; a Raid was conducted on or about February 18, 2009. More than fifty officers participated during a month of heavy snow on an early evening of regularly scheduled Surgery and Medical care. There were representatives from the Federal Bureau of Investigation, The Drug Enforcement Administration, PA Department of Health, Philadelphia Detectives and Philadelphia Police Officers. Multiple Media Representatives and their equipment displayed a prominent presence.

A frenzy of media exploitation with "villainization" and "monsterization" ensued until present times on Local, National and International levels with compromise to constitutional rights to due process.

## BACKGROUND:

Defendant was reared by both parents who were descendants of rural Southern farmers as well as former slave ancestry. At the age of eleven, Segregation prevented his admission to the neighboring West Branch Young Men's Christian Association. He was a Civil Rights Demonstrator from fifteen years of age. Academic achievement allowed him to attend highly rated Dimmer Beeber Junior High and Central High School. Defendant was accepted at the Medical School of his choice (Thomas Jefferson in Philadelphia) at a time when most Negro Americans attended Minority facilities which were significantly less endowed. Mercy Douglas Hospital was the only hospital open to minorities upon his graduation and after his Internship. He was the first Negro American accepted to be a Resident at that Thomas Jefferson University in Obstetrics and Gynecology.

An academic career in Gynecologic Endocrinology was planned with acceptance to a M.D./Ph.D. program. Doctorate Studies were to be with Dr. Sam D'Angelo with the emphasis on Hypothalamic Research, facilitating an emphasis on Male and Female Infertility. The Sub Specialty was compatible with his commitment to retain relevance to Social Change. The opportunity for immediate involvement in minority issues presented itself and he obtained a leave of absence from his training.

Formerly a Volunteer Physician in the Free Clinic of The Young Great Society under leadership of Herman Wrice, Defendant rapidly became Medical Director of their Narcotic Rehabilitation Program. Provisions included Ambulatory Detoxification and the sole city setting providing Inpatient Detoxification for Women. A ten year experience in Methadone Maintenance ensued. His training with Drs. Dole and Nyslander was augmented by the influence of Avram Goldstein. Low dosage Maintenance became the Primary modality with emphasis on Detoxification with a "blind dosage" format. This program suffered greatly from the cutbacks in Federal Funding for Human Services under "Reaganomics". Significant occurrences, during this experience included Federal Certification for Methadone Maintenance; Authorization for evaluation of long acting Methadone (LAAM) for the Federal Drug Authority under James Whysner Associates; Supervision of Psychiatrists and Supervision by Psychiatrists (notably Maurice Linden, M.D. and Jon Bjorenson, M.D.); Psychoanalytic training and supervision by Dr. Paul Mestancik; publications in numerous local magazines and frequent Television appearances; regular Radio interactive interviews; Publications including Alumni Magazine of Thomas Jefferson University, Journal of the Philadelphia Country Medical Society, and Proceedings of the International Council of Alcoholism and Addictive Diseases in Warsaw, Poland. Poetry of Defendant has been published in a variety of venues - including Dickinson College Bulletin, Philadelphia Magazine, Buddhist Newsletter and a recent Documentary (3801 Lancaster Avenue).



Defendant's long term commitment to Community Need has never abated but his Honorable Discharge from Military Service in order to continue his Community Narcotic Rehabilitation endeavors has greatly strengthened the resolve to sustain his priority to Decriminalization and Innovative Treatment Approaches. He had received a "Berry" deferral for the duration of his Obstetrical and Gynecologic Training. During his leave of absence and work in Community Medicine, he was activated for assignment as a Medical Officer in Viet Nam. After notification of his work in Narcotic Rehabilitation in deference to completing his M.D./Ph.D. program, the assignment became Military Opiate Detoxification for Addicted Combatants, again in Viet Nam. The Community response to the loss of his expertise and Direction in Community Medicine and Addictive Disease was substantiated by more than three thousand written letters of support. The Intervention of Henry Stein, Esq. of Mesirov, Gelman, Jaffe, Levin, Cramer and Jamison resulted in the Honorable Discharge as cited above.

Presently, self help manuals are in the process of completion for publication: Personal Health and Welfare, Addictive Disease and Mental Health. The foundation for these initiatives is the emphasis, over forty clinical years, of preventive health care, supportive medications and psychotropics as necessary, and the long term goal that the individual thrives with coping skills which progressively eliminate the dependence on substances. A major accomplishment of these early years was the certification of Mantua Human Services as Philadelphia's sole independent facility for Mental Health. For several years, Defendant was also Medical Director of Model Cities Drug Treatment Program/Alternatives; for the City of Philadelphia.

Women's Medical Society was also maturing during these early clinical years. Located in a Medical Office Building on the campus of the University of Penn., family care was provided for the Mantua patients and the community, as well as abortion and family planning. Family Medical Society highlighted the growth to a center for more than simply the care of women. Society, rather than Services, connoted an extension of the concept that "it takes a village to raise a child." The advantage of family treatment was first evidenced in the virtual elimination of genital warts, human papillomavirus (HPV). Later, early HIV treatment effected undetectable viral loads. The second clinical decade was marked by a forced relocation to a community setting. A building, abandoned for ten years was purchased and renovated with a \$95,000 loan from the Small Business Administration. Arlene "M" was the Architect, Defendant the major contractor, Val "M" the supervisor of the workforce of patients recovering from heroin dependency. The concept of Bonsai Therapy was spawned. The constraints of past trauma would limit one's potential. But a person, just as a building, can be rehabilitated, earn respect and even acclaim.

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Abortion services evolved over a period of years. Two presentations liberalized the policies of the ObGyn department of Thomas Jefferson Hospital in the late 1960's. Dr. John Franklin, better known for his Midwifery program at Booth Maternity Center, presented the medical imperatives for pregnancy terminations. This aspect is known in many Academic settings as "Abortion for Cause." Dr. Gosnell, a Resident in training, presented the Sociologic realities of avoiding lifelong poverty. A disturbing documentary on the plight of the poor by United Press International's Bud Outlaw turned visual images into policy change. It was generally expected that the PA Abortion Control would be determined to be unconstitutional. And it was. Thus, when the Clergy Consultation Service recruited Dr. Gosnell for the Nation's first ambulatory abortion facility in New York City, and very shortly after *Rowe v. Wade*, Defendant was well experienced in Dilatation and Curettage (D & C). Private practitioners and clinics are often more responsive and innovative compared to academic meccas. In this instance, the suction curettage, taught by Dr. Hale Harvey of New Orleans, was vastly superior - in regard to safety, comfort, time and cost. But pace and haste of five treatment rooms, another patient every fifteen to twenty minutes with the priority of meeting airline connections became overwhelming aberrant and even abhorrent, despite the financial advantage to the community medical care. When Dr. Gosnell returned full time to Philadelphia, there were concerns among the New York clinicians that referrals from Pennsylvania would be adversely affected. And rumors of professional incompetence were disseminated. Interstate factors directed the ensuing investigation to a Federal Agency. Dr. Beach Conger was responsible for the review of the three months in NYC. One thousand and sixty seven procedures and no complications.

There was a ten year interval with the priority of responsive whole person medical services. While espoused as optimal, the time necessary to address the underlying issues of major complaints was cost prohibitive for financial stability. Thus, medical care became a "loss leader" and business needs were bolstered by the Family Planning services at times, and at times by the income from the provision of treatment for Addictive Diseases. The disconnect in medicine was that the same Institutions who taught Whole Person care actually, in a highly competitive reality, had no option except to play "Baseball Care". Every patient had to "touch" every reimburseable base. Strict adherence to boundaries of each specialty became an unspoken rule. Advertising and aggressive public relations for "Big ticket" care became usual - as with Joint Replacement surgery. All too usual, also, was the three day observation in Coronary Care Unit when even obvious musculo-skeletal pain happened to be left sided and there was medical insurance. Capitation of medical care severely worsened the problem, especially in Mental Health as the interdisciplinary care was further fragmented. But under the Defendant approaches, a patient with cancerphobia could receive a monthly abdominal ultrasound for reassurance; an Alcoholic could work towards controlled drinking after exploring alternative coping skills such as music; couples could receive medical counseling when their symptoms were merely "masks"; students with academic problems received tutoring in math; smokers were introduced to alternative coping skills; and there was much appreciation and success of the "No Hunger Diet". And the Defendant began sixteen years of competitive Triathlons at the age of fifty, exemplifying the advantages of a healthy and vigorous lifestyle.

Patients who were not in crisis tended to opt for more convenient and traditional medical care. The waiting was usually long, at times inordinately long. Late night appointments were not always preferred and patients in crisis were sometimes objectionable. One of the first pain management patients was a well known local artist with metastatic cervical cancer. Her family reported that only her medications allowed her to continue her painting and family responsibilities. Medications to improve functional levels became routine and often included Psychotropics. A daily variance in symptoms was expected as the setting became comfortable and responsive to those considered to be mentally ill. Neuroses were viewed as exaggerations of normal responses. The stimulus of two times four might yield a reaction of sixteen or sixty four. In a Psychotic, a stimulus of three times five might result in green, chartreuse, or rage. In these instances, acceptance and then modification and later cessation was encouraged as the goal of insight was pursued. A not unusual question asked, "How are the voices today?" Over time, the Basic Tools of Mental Health evolved: The Psychosocial History (the story of a person's life); The Mood Questionnaire (Triggers that Evoke Emotion); and the Life Plan (How to Flourish without Substances).

A pharmaceutical representative of family planning settings encouraged the Defendant to extend his therapeutic acumen beyond the first trimester. Sharing the techniques and observations of other clinicians, the importance of specific instrumentation for various gestational weeks was firmly established. The modest investment of Berkeley Suction curet to size 16 facilitated the usual termination without incident to 17 gestational weeks. As significant as the advantage of Pratt versus Hegar dilators, were these examples of cost and safety effectiveness: Brierer forceps versus Sopher; lateral wall retractors; weighted and Peterson speculi; extra large speculi; operative ultrasonography; ultrasounds with vaginal probe capabilities; Hearn forceps; Hearn's forceps without "teeth"; automatic lift exam tables; operative ceiling lighting; automatic operator doors; hygienic treated upholstery for exam tables, chaises and chairs; and dental standard surfaces for operatories and cabinetry. The purchase of four pulse oximeters was expensive but deemed essential for patient safety. These acquisitions over more than twenty years, reflect a gradual evolution of services, stimulated by presentations, exhibitions by marketers, and individual conferences and relationships with experts of the National Abortion Federation. As a result of the above, Defendant was considered by his colleagues to be a capable and appropriate provider of terminations to 24 gestational weeks. The perspective that suction curets were labeled as "one time use" in approximately 1980 looms important. Cidex sterilization has long term been the standard of care, and the transition was more profit than safety oriented.



Particularly instrumental in the above cited developments were the presentation and personal communications with Dr. Martin Haskell. His technique called Dilatation and Extraction was designed to prevent the need for uterine forceps, as his training was not Obstetrical but consisted of Surgery and Anesthesiology. Later publicized as the "Partial Birth Abortion", the methodology provided significant maternal advantages and decreased risk of complications. Over a number of years, Defendant participated in Food and Drug Authority studies for Ortho Pharmaceuticals, primarily with androgenic progestins. He also became a frequent marketing consultant for both general medical and Family Planning medications. Subsequently, he was drawn to the clinical benefits of the Estrogenic Progestins and the dosage shortening of Warner Chilcott and became a frequent contributor to the TRENDS conferences - Trends in Women's Healthcare. An Harvard Assistant Professor of ObGyn introduced Defendant to Dr. George Tiller as his own personal mentor. He had been assisting in first trimester suction curettage while still an undergrad at Penn. Dr. Tiller and Defendant became colleagues and friends as they discussed their comparative risks based on their respective patient populations and the impact of the "Browning of America" and the anti-abortion movement.

The medical center had grown substantially over the years. With a modest investment and extensive "sweat equity", it had become an owned facility with 4900 sq.ft. of administrative and clinical offices. The second land acquisition converted October Gallery into two surgical operatories, handicap access and bathroom, recovery room, two examining offices, a pediatric examining area and two additional bathrooms. This expansion had taken more than two years. Again, Defendant was the major contractor but under the direction of the Architect, Bill Brown. The expansion represented the reinvestment of ten years of profits. But a loan of \$47,000 was a necessity for completion of dental standard cabinetry and walls, the operative ceiling lighting, automatic opening doors and \$6400 for four pulse oximeters. Monthly improvement projects included crown molding throughout all buildings, mirrors and terrariums for all bathrooms, wainscoting at the back of all chairs, anti-bacterial upholstery for all chairs, chaises and exam tables; foot molding for all walls and commercial tiling for all floors. The hobbies and interests of Art, Photography, Tropical Fish and Horticulture provided a dominant presence. Two fluorescent basement enclosures provided forced "spring time" and Defendant's annual winning of prizes at the Flower Show of the Pennsylvania Horticultural Society. By 2007, a third Architect had been had been commissioned for a second floor and separate entrance for an gym/exercise area, above the medical record room. Deposits and plans for electronic records had been instituted. The recession and the monthly \$8000 for malpractice coverage markedly slowed growth and development and threatened survival.

In 2007, the United States Supreme Court was deciding that the "Partial Birth Abortion" could not be the primary modality of late term abortion. The crux was the ethics of performing an act which would kill the up to that point viable fetus. Although a decision had not yet been decided, Dr. Tiller presented, recommended and instructed on Digoxin fetal injection as protection for both the clinician and the patients from violation of the law. The presentation and personal communications regarding the subtleties of Cytotec by a lecturer from Britain were similarly instrumental. Telephone consultations with Dr. Tiller were often two to three times a week as Defendant introduced new methodology into his clinical framework. There were progressive modification of Digoxin dosage and placement; cervical dilation with laminaria and Dilapan; documentation of informed patient consent; and augmented administration of oral and vaginal Cytotec. Experiencing the death of a patient in 2002 from uterine perforation and sepsis; and sensitive to fetal pain from "Primal Scream", Defendant was confident in the benefits of Induced Fetal Demise. The method was legal, more humane (even with the incidence of spontaneous expulsion) and there was no risk of uterine perforation.

Possibly due to the stringencies of the recession, a decreased incidence of abortions was a national phenomenon. The agency's malpractice fee had been lowered \$140,000 in annual premium. There had not been additional charges after the death of 2002. But the present premium lacked any concern for lowered income and was constant as Pennsylvania has not promulgated Tort coverage. Financial survival fell upon the late termination referrals from Delaware, Maryland, Virginia and the District of Columbia. Defendant emphasis on cost containment earned results. Services here of \$1200 were priced above \$2500 in the above settings. And the patients and their referring physicians were overwhelmingly pleased. The decrease in Family Planning services allowed more time to respond to patients with Mental Health and Pain Management problems. The patterns were infinitely similar, almost identical, to Defendant's early experiences in the decriminalization of Heroin. There was the same relief, being treated like a person and not as an addict. There was the same high incidence of significant trauma. There were the same patterns of parental inadequacies and inappropriate peer pressure. Criminal involvements were the customary methods of sustenance. But it was a more dangerous and angrier population. For the first time, Defendant needed regular security. But same pattern of results was expected. Over the years, despite the substance in popular vogue, the results had been constant. About 25% would benefit long term - probably those most highly motivated. Approximately 50% would improve so long as they received their substance of choice. And approximately 25% would be "conning". The bulk of the symptomatology was musculoskeletal except for the wounded Veterans, the Cancer patients and those with medical/surgical complications.



With the experience of a triathlete in these problems and the advice of "former abusers", Oxycontin was limited to those with confirmation of a Radiculopathy within several months of the Pain Management program; Phenergan with Codeine only in limited amounts to the smoker's with Bronchitis. Defendant bore the brunt of the workload. A severe winter mandated a "holding pattern" for musculoskeletal pain and Defendant was certain of additional help by the Spring. Probably, again, from the staff and students of the Philadelphia College of Pharmacy and Science. Until then, sixteen hour days, 6-7 days per week and no more than 25 new patients on Tuesday, Thursday and Saturday evenings into the early mornings. It appeared that the Mental Health needs had found its long term funding source and that rehiring from the attrition from recession could be instituted.

The winter of 2006 to 2007 was severe and many storms were experienced. Philanthropic funds of five million dollars were granted to Planned Parenthood and to the National Abortion Federation to assure supplemental abortion funding for underprivileged women. It was months, however, before the deleterious impact on the market share of patients who normally utilized defendant's services. These monies had been long anticipated and NAF membership had finally become cost effective. Membership would mean both referral of patients and financial support for their procedures. Prior to this, the additional fee of more than \$2000 annually could not be afforded. Eighteen months after the application process, the mandatory site inspection was performed, on or about November 7, 2006. As customary in NAF certifications, site deficits would be followed by action plans and reinspections. Importantly, the facility deficiencies were primarily administrative; not surgical, sterility, equipment, professionalism or quality standards of patient care. The absence of a full time Administrator and Staff had never been afforded. The agency policies and procedures were in revision; rapidly evolving with new methodology; and their presence was essential to NAF standards.

There were a number of complicating factors. Two key family members had been absent from the staff. The full time receptionist, Defendant's Mother, had died from a tragic home accident. The Nurse Administrator, Defendant's Aunt, was on extended medical leave for a series of malignancies to which she eventually succumbed. The patterns of trust from more than twenty years of daily family support proved costly. [

Shortly before the site inspection, a patient experienced a cardiac arrest in an otherwise uneventful seventeen week abortion. CardioPulmonaryResuscitation was instituted immediately but prolonged intervention by Emergency Medical Technicians was necessary before hospital triage was possible. Cardiac activity was eventually achieved but cerebral damage was confirmed. Life supports were discontinued on the following day. There was no surgical complication or perforation. The analgesia was a combination used by Defendant at usual dosage for thousands of patients over forty years. Defendant was at a loss to explain the cause but in the initial coroner's report was accidental death.

Defendant was returning from Surgery in Delaware as he approached his offices on a crisp February late afternoon which was almost like spring, despite the forecast for more snow. The plethora of police vehicles and vans; officers; television equipment from all the major channels; and hoses and cables across the roads was surprising and striking - probably another killing at Scooters was surmised. This neighboring bar often experienced two homicides a year. The reality, however, was a Raid by the Federal Bureau of Investigation, Drug Enforcement Administration, Pennsylvania State Board of Health, Philadelphia Police and Detectives, Crime Scene Investigators and Photographers with many, many assistants. The media frenzy, often with false accusations, yielded local, national and international levels of sensationalism. The sharply augmented incidence of laws promulgated against the providers of abortion is evidence sufficient that the political target extended far beyond this defendant. Dr. George Tiller was shot and killed while passing the collection plate at Church. Dr. Gosnell was only investigated, castigated, persecuted, monsterized, prosecuted, convicted and incarcerated.

## ADDENDUM TO MEMORANDUM IN SUPPORT OF § 2255 MOTION

Defendant is confident of eventual vindication. The Supreme Court of the United States has already ruled and formalized an opinion in regard to lethal fetal injection which supports his Appeal Grounds of Wrongful/Illegal Sentence. The Third District Court of Appeals has already ruled with opinions which support defendant's affirmations of prejudicial, inflaming semantics, underscoring judicial bias and the importance of any appearance of Impropriety or IMPARTIALITY. Perhaps most compelling is the clarity of the law expressing that there is no crime without willful intent.

Gonzales vs. Cechart, 550 U.S. 124 (2007)  
Planned Parenthood of Central New Jersey  
vs. Farmer, 220 F.3d 127 (2000)  
Legal Ethics - Rotunda & Dzienkowski

The initiatives of Petitioner may be significant. Three Self Help Manuals are being submitted for publication: Addictive Disease; Mental Health; and General Well-being. Proposals for the Criminal Justice Balance are entitled "Better Outcomes for Prisoners", 804P. The populations for intervention are: Inmates incarcerated for more than 25 years; those with crimes before the maturity of 25yrs; those Not Guilty of the Crime of Conviction; Correctional Officers as Mentors; and inmates who better could contribute to society. A quintet of poems, submitted for publication, are: Twenty Five years of being the empty chair; Quicksand; Prison Lives Matter; C.O.'s are people, too; and Why Jail Me ?

An educational fund, planning to become a foundation is dedicated to Petitioner's parents. Two projects of many years duration have been Extracurricular Activities and Academic Performance and Neuro-Endocrine Immune Competence, Stress Intervention and Neoplasia.

Two clinical presentations are awaiting access to the Office and Data of Petitioner. Sexual Intactness in patients with Clitoral Surgery - more commonly known as sexual mutilation. These writings are an outgrowth of the Infertility interventions in immigrants from Africa. Secondly, the rate of Spontaneous Expulsion with Dilators, Digoxin Fetal Injection and Cytotec.

MOTION § 2255

Page 24

**ALBERTO R. GONZALES, ATTORNEY GENERAL, Petitioner**

**vs.**

**LEROY CARHART, et al.**

**ALBERTO R. GONZALES, ATTORNEY GENERAL, Petitioner**

**vs.**

**PLANNED PARENTHOOD FEDERATION OF AMERICA, INC., et al.**

**550 US 124, 127 S Ct 1610, 167 L Ed 2d 480, 2007 US LEXIS 4338**

(No. 05-380), (No. 05-1382)

**Argued November 8, 2006.**

**Decided April 18, 2007.**

### **DECISION**

Partial-Birth Abortion Ban Act of 2003 (18 U.S.C.S. § 1531) held not to facially violate Federal Constitution by allegedly (1) being vague; or (2) imposing undue burden on woman's right to abortion on basis of (a) asserted overbreadth or (b) lack of mother's-health exception.

*Prior history:* 413 F.3d 791, 2005 U.S. App. LEXIS 13561; 435 F.3d 1163, 2006 U.S. App. LEXIS 2315

### **SUMMARY**

Medical uncertainty does not foreclose the exercise of legislative power in the abortion context any more than it does in other contexts. Other considerations also support the Court's conclusion, including the fact that safe alternatives to the prohibited procedure, such as D&E, are available. In addition, if intact D&E is truly necessary in some circumstances, a prior injection to kill the fetus allows a doctor to perform the procedure, given that the Act's prohibition only applies to the delivery of "a living fetus," 18 U.S.C. § 1531(b)(1)(A). *Planned Parenthood of Central Mo. v. Danforth*, 428 U.S. 52, 77-79, 96 S. Ct. 2831, 49 L. Ed. 2d 788, distinguished.



PLANNED PARENTHOOD OF CENTRAL NEW JERSEY; HERBERT HOLMES, M.D.; DAVID WALLACE, M.D.; GERSON WEISS, M.D.; on behalf of themselves and their patients v. JOHN FARMER, JR. \*, Attorney General of the State of New Jersey, in his official capacity, and his successors in office; NEW JERSEY BOARD OF MEDICAL EXAMINERS, and their successors in office; CHRISTINE GRANT \*, Commissioner of the Department of Health and Senior Services, in her official capacity, and her successors in office; NEW JERSEY LEGISLATURE, by and through DONALD T. DIFRANCESCO, in his official capacity as President of the New Jersey Senate, and JACK COLLINS, in his official capacity as Speaker of the New Jersey Assembly, and as the representative of the New Jersey Assembly, (Intervenors in D.C.), Appellants

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

220 F.3d 127; 2000 U.S. App. LEXIS 18050

Nos. 99-5042 and 99-5272

November 19, 1999, Argued

July 26, 2000, Filed

Opinion by: BARRY

### Opinion

The Legislature's argument that Roe and Casey are inapplicable to "partial-birth" abortion procedures because such procedures are infanticide rather than abortion is based on semantic machinations, irrational line-drawing, and an obvious attempt to inflame public opinion instead of logic or medical evidence. Positing an "unborn" versus "partially born" distinction, the Legislature would have us accept, and the public believe, that during a "partial-birth abortion" the fetus is in the process of being "born" at the time of its demise. It is not. A woman seeking an abortion is plainly not seeking to give birth.

Moreover, that the life of the fetus is terminated when a "substantial portion" has passed through the cervix and is in the vaginal canal, does not without more transform an abortion procedure into infanticide. Again, the medical evidence clearly indicates that in many conventional abortion procedures the fetus may be killed, i.e. the heart ceases beating, when a substantial portion of the fetus (whether it be disarticulated limbs or part of the body of {220 F.3d 144} the fetus) is in the vagina and a portion remains in the uterus. In what can only be described as a desperate attempt to circumvent over twenty-five years of abortion jurisprudence, the Legislature would draw a line based upon the location in the woman's body where the fetus expires. Establishing the cervix as the



# THE PROBLEM OF F

The makers of O  
By Jonah Camp

In December 1995, the Food and Drug Administration approved Purdue Pharma's prescription painkiller OxyContin for sale in the United States. The active ingredient in the drug is the opioid oxycodone, a narcotic in the same chemical family as morphine, codeine, heroin, and methadone. Opioids have long been used in the treatment of cancer pain and in palliative therapies, but for most of the twentieth century they were thought to present too great a risk of addiction and abuse to be used for chronic non-cancer pain. Oxycodone offers powerful pain relief, but it can also deliver a euphoric high and in large doses can lead to respiratory failure. OxyContin, however, came with a special claim: its extended-release formulation—inactive binders were added to slow the absorption of the drug into the bloodstream—was “believed to reduce the abuse liability” of the drug. Or so read its label, in spite of the fact that scientists from both Purdue and the FDA had noted the ease of extracting most of the pill's oxycodone dose by crushing the pill and dissolving it in water. Purdue eventually acknowledged the risks of OxyContin but continued to sell the drug until 2010. In March 2013, the company sent this letter to the FDA asking the government to withdraw its approval of OxyContin. (We obtained the letter through a Freedom of Information Act request.)

OxyContin's path from FDA approval to withdrawal began in the late 1980s, when a small but growing number of clinicians and researchers began arguing that America was suffering from an “epidemic of untreated pain.” Purdue built alliances with these critics of the medical establishment's “opiophobia” and devoted millions of dollars to pain-management research. Once OxyContin was launched, the company mounted an ambitious and wildly successful marketing campaign that touted the drug's safety and effectiveness for an ever-widening array of conditions, from back and neck pain to pain associated with arthritis, migraines, kidney stones, diabetes, and fibromyalgia, as well as postoperative and postherpetic pain. (Purdue even claimed in promotional materials that the drug improved the mood of its users and helped them sleep.) In 2002, doctors wrote 6.2 million prescriptions of OxyContin for non-cancer pain, a tenfold increase from 1997, and rates of prescription-drug abuse rose at a similar pace. The FDA, the Drug Enforcement Agency, and Purdue scrambled as the epidemic of untreated pain gave way to an epidemic of prescription-opioid abuse. In 2001, OxyContin's label was changed to include a more strongly worded warning, and the claim about the drug's reduced abuse liability was removed. In 2006, deaths from prescription-opioid overdose surpassed those from heroin and cocaine, with OxyContin, according to the FDA, “at the center of the problem.” By 2011, nearly 17,000 people a year were dying from opioid-related poisoning in the United States.

In 2007, Purdue and three of its top executives pleaded guilty in federal court to fraudulently marketing OxyContin. The case resulted in a settlement of \$600 million from Purdue and \$34.5 million from the executives themselves. (To date, Purdue has grossed more than \$27 billion in sales of OxyContin in the United States alone.) The company admitted to knowingly misrepresenting the addictive potential of the drug in its promotional materials and its presentations to doctors. A 2011 investigative report by the *Milwaukee Journal Sentinel* revealed that the University of Wisconsin Pain and Policy Studies Group, an influential pro-opioid pain-management research center, had quietly accepted \$1.6 million from Purdue, among donations from other opioid manufacturers. In 2012, the Senate launched an investigation into Purdue's financial relationships with a number of prominent individuals and organizations in the field of pain medicine. Soon thereafter, one of these organizations, the American Pain Foundation, announced its immediate dissolution due to “irreparable economic circumstances.”



March 19, 2013

REQU  
APPR

Bob A. Rappaport, M.D., Director  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Anesthesia, Analgesia,  
and Addiction Products  
5901-B Amundson Road  
Beltsville, MD 20705-1288

Re: Original OxyContin® (oxycodone hydrochloride controlled  
NDA 020653, Sequence 0079)

Dear Dr. Rappaport:

Reference is made to Purdue's August 10, 2010 correspondence  
had ceased shipment of the original formulation of OxyContin (b  
reformulated OxyContin (NDA 022272). Also refer  
correspondence requesting that NDA 020653 be moved to the  
Book.

Purdue hereby requests withdrawal of the approval of NDA 02  
OxyContin, pursuant to 21 C.F.R. 314.160.

The original formulation of OxyContin was safe and effective i  
United States, that formulation was subject to abuse, misuse,  
other entities took steps to mitigate these risks, over time it b  
permitted in the U.S. despite all other significant efforts to mi  
developed a new formulation of OxyContin which was specif  
manufactured to be resistant to common forms of manipulat  
the original formulation. In particular, reformulated OxyCont  
crush, or to dissolve into a solution suitable for injection, co  
individuals intent on abusing the product. Reformulated Ox  
variety of *in vitro* and *in vivo* settings designed to simulate  
Based on these data, Purdue concluded that the reformula  
the original, and discontinued the original formulation (NDA  
approved and launched in August 2010.

Purdue is conducting eleven epidemiologic studies, six of  
commitments to the Agency. Purdue has provided regulat  
to NDA 022272 and IND 029038. Epidemiologic data an  
reformulated OxyContin has resulted in a decrease in mi

Dedicated to Physicians an  
Sincerely,

(See appended elec  
Beth Connolly  
Associate Director, F

Withdrawn a  
that, after approval of  
safety impact of the re  
(a) or (b) (i.e., paragraph

A T I O N

# AIN MANAGEMENT

OxyContin play dirty  
and Simon Liem

Purdue Pharma L.P.

Standard Form  
FD-302 (Rev. 05-08-10)  
www.fda.gov/oc/2010/05/08/10-05-10

WITHDRAWAL OF  
NDA 020553

Purdue Pharma L.P.

On August 11, 2010, the Agency that Purdue (NDA 020553) and had begun the withdrawal of the Orange

for the original formulation of

been as directed, but, in the diversion. While Purdue and it is apparent that these risks are them. Concurrently, Purdue also designed, tested, and associated with abuse and misuse of has been made significantly harder to techniques employed by has been extensively tested in a is to abuse or misuse the product. product others. Safety advantages over (NDA 020553) when the reformulation was

are required by post-marketing studies on these studies in submissions to date show that this introduction of and abuse of OxyContin in the U.S.

Additional information, please contact me directly via telephone at Beth.Connelly@pharma.com.

Signature page

Legal Affairs

21 C.F.R. 314.150(c) does not appear to be appropriate because Purdue believes formulation of OxyContin and in light of the current database regarding the situation (as referenced above), one or more of "the conditions listed in paragraphs (2)(i) or (ii) apply to the drug."

Jonah Campbell is a research assistant at the McGill University Biomedical Ethics Unit and the author of *Food & Trembling (Invisible)*. Simon Liem is a journalist living in Montreal.

Before Purdue removed OxyContin from the market in 2010, it received approval from the FDA for a new version of the drug. The reformulated OxyContin was identical to the original but contained a polymer that made crushing and dissolving the pills more difficult, which was intended to discourage snorting and injection. Purdue registered a set of patents on the reformulation that would effectively extend its monopoly on the drug until 2025. The company waited until one month before the original patents expired—when generic versions would have become legal—to send the withdrawal request reproduced here. Purdue argued that since it had provided a safer alternative to its own creation, permitting the sale of generic OxyContin would pose an unacceptable danger to the public. The company maintained that the old version was and had always been "safe and effective," but that for "reasons of safety" a prohibition was now necessary. Jacob S. Sherkow, an associate professor at New York Law School who specializes in biotechnology and patent litigation, calls the letter a "naked effort to ensure market exclusivity by hook or by crook."

On the day before the original OxyContin patents expired, the FDA delisted the drug. The agency and Purdue cited early epidemiological data indicating that the tamper-resistant features of the reformulated pill were somewhat effective at reducing abuse. (A *New England Journal of Medicine* survey found that two thirds of recreational OxyContin users switched to another opioid after the reformulation; heroin was the most popular alternative.) Generic manufacturers, which were thus barred from producing the original formulation, sought to challenge the new patents. In January 2014, Teva Pharmaceuticals won its case against Purdue, and the patents were ruled invalid. Purdue is appealing the decision and has claimed that a different patent, one that Teva did not challenge, still protects the new drug. That patent does not expire until 2017, and Teva has not yet started selling a generic version of the new OxyContin.

Since the introduction of the reformulation, Purdue has petitioned the FDA to adopt formal requirements that any oxycodone generics must have the same abuse-deterrent features as OxyContin. To date, the FDA has resisted Purdue's lobbying. Margaret Hamburg, the FDA's commissioner, told a Senate committee that Purdue's abuse-deterrent technology was "poor": "It doesn't prevent abuse or misuse when taken orally. And it's, frankly, not where we need to be." The FDA did, however, approve labeling for the reformulated pills that allows Purdue to advertise its new safety features, and at least until the lawsuits against generic manufacturers are resolved, the company remains the sole vendor of extended-release oxycodone pills. After nearly twenty years of failure and malfeasance, and as the number of prescription-opioid overdoses continues to rise, Purdue is once again claiming that OxyContin deters abuse. ■